

Remarks/Arguments

Claims 1, 5, and 8-11 are amended. Claims 2-4, 6, and 7 are canceled without prejudice. Claims 1, 5, and 8-30 are pending in the application. Claims 12-30 are withdrawn. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Interview Summary

On May 5, 2010, Patent Agent Natalie Davis conducted a telephone interview with Examiners Gyan Chandra and Robert Landsman. During the interview, the parties discussed the Office Action dated December 11, 2009. Specifically, the Widera reference and proposed amendments were discussed. No agreement was reached during the interview.

Applicant would like to thank Examiners Gyan Chandra and Robert Landsman for the courtesy of granting a telephone interview with Patent Agent Natalie Davis.

Specification

The Brief Description of drawings stands objected. More specifically, the Office Action states that because figure 8 comprises two views labeled as "(a)" and "(b)," the Brief Description should be labeled as "Figures 8 (a) and (b)." Applicant respectfully traverses this rejection.

The MPEP at 608.01(f) states the following:

"When there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures,

and to the different parts by use of reference letters or numerals.” (see 37 CFR 1.74)

37 CFR 1.74 does not require that the Brief Description be labeled in a specific manner as stated in the Office Action. 37 CFR 1.74 only requires that all of the views of the drawings be labeled and described. The specification on page 6, at lines 25-29 provides a description of both views (a) and (b) that are shown in figure 8 of the drawings. As such, figure 8 in the Brief Description of drawings is in compliance with 37 CFR 1.74 and the objection should be withdrawn.

Claim Rejections Under 35 USC § 112 Second Paragraph

Claims 10-11 stand rejected 35 U.S.C. § 112, second paragraph as being indefinite.

More specifically, the Office Action states that the metes and bounds of the claims cannot be determined because the claims recite that the Tf domain comprises iron molecules. Applicant respectfully traverses this rejection.

Claims 10-11 have been amended to recite that the Tf domain may bind iron molecules, thus rendering this rejection moot.

Claim Rejections Under 35 USC § 102

Claims 1-6 and 9-11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Widera et al. (Pharm Res. 20:1231-1238, 2003 (August)). This rejection is moot with respect to claims 2-4, 6, and 7 due to the cancellation of these claims. Applicant respectfully traverses this rejection as to claims 1, 5, and 9-11.

Claim 1, as amended, is as follows:

A fusion polypeptide comprising a granulocyte colony stimulating factor (G-CSF) domain operably linked

to a transferring (Tf) domain, wherein the ability of the polypeptide to be transported into a cell expressing a transferring receptor (TfR) gene or the ability of the polypeptide to be transported across a cell expressing a TfR gene via transcytosis is higher than that of the G-CSF domain alone.

Applicant respectfully submits that Widera cannot anticipate or render claim 1 obvious, because Widera fails to teach or suggest at least a fusion polypeptide comprising G-CSF and Tf, as set forth above. Instead, Widera discloses a conjugate comprising G-CSF and Tf. Widera does not teach or suggest to use a fusion protein. Nor does Widera disclose any possible advantages a fusion protein may have over a conjugate.

It is an aspect of the present invention that G-CSF-Tf fusion proteins may be produced in large quantities with a high degree of purity, exhibit a higher efficacy than a conjugate in a body or cell, remain intact in a cell or body, and have a longer half-life. In contrast, conjugates produce mixtures of heterogeneous protein aggregates and are thus impure, have lower half-lives and may dissociate inside a cell or body (Applicant's specification, at p. 23, line 25-p. 24, line 10).

In light of the foregoing, Applicant respectfully submits that Widera cannot anticipate or render claim 1 obvious, because Widera fails to teach or suggest each and every claim limitation. Claims 5 and 9-11 depend from claim 1 and cannot be anticipated or rendered obvious for at least the same reasons as claim 1. Withdrawal of this rejection is thus respectfully requested.

Claim Rejections Under 35 USC § 103

Claims 1, 3, and 5-7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Widera in view of Friden et al. (U. S. Patent No. 5,672,683). This rejection is moot with respect to claims 3, 6, and 7 due to the cancellation of these claims. Applicant respectfully traverses this rejection as to claims 1 and 5.

Claims 1 and 5 are patentable over Widera for the reasons discussed above. Friden cannot remedy the defect of Widera and is not relied upon by the Office for such. Instead, the Office cites Friden for teaching making a fusion protein between transferrin and CNTF using a Leu-Glu linker.

In light of the foregoing, Applicant respectfully submits that the cited references cannot render claims 1 and 5 obvious, because the cited references fail to teach or suggest each and every claim limitation. Withdrawal of this rejection is thus respectfully requested.

Claims 1, 3, 5, and 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Widera in view of Prior et al. (U. S. Patent No. 7,176,278). This rejection is moot with respect to claim 3 due to the cancellation of this claim. Applicant respectfully traverses this rejection as to claims 1, 5, and 8.

Claims 1 and 5 are patentable over Widera for the reasons discussed above. Prior cannot remedy the defect of Widera and is not relied upon by the Office for such. Instead, the Office cites Prior for teaching making expression construct comprising a transcriptional promoter, a secretory signal sequence, a DNA sequence encoding a modified Tf fusion protein, wherein transferrin protein is joined to a DNA encoding a therapeutic protein of interest.

In light of the foregoing, Applicant respectfully submits that the cited references cannot render claims 1 and 5 obvious, because the cited references fail to teach or suggest each and every claim limitation. Claim 8 depends from claim 5

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and cannot be rendered obvious for at least the same reasons as claim 5.
Withdrawal of this rejection is thus respectfully requested.

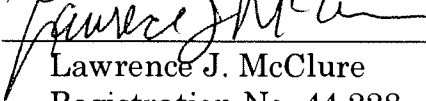
In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (310)785-4600 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,
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Date: June 10, 2010

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